

REMARKS

Claims 1, 3-5, 11-15 and 21-34 are presently pending in the case. The claims have not been amended. Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Allowable Claims

Claims 1, 3-5, 11-15 and 21-34 were allowed in an *Ex parte* Quayle action in the Office Action dated October 31, 2007. Inexplicably, the allowance was withdrawn in the Office Action of April 16, 2008, in favor of the improper rejections described below.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 1, 3-5, 11-15 and 21-34 under 35 U.S.C. §03(a) as being unpatentable over U.S. Patent No. 6,116,237 to Schultz et al (hereinafter Schultz et al) in view of U.S. Patent No. 5,855,913 to Hanes et al (hereinafter Hanes et al) and U.S. Patent No. 5,049,389 to Radhakrishnan (hereinafter Radhakrishnan). The rejection is traversed.

Schultz et al, Hanes et al and Radhakrishnan do not render independent claim 1, for example, unpatentable. Claim 1 is to a method comprising, *inter alia*, loading a dry powder composition into a passive dry powder inhaler. Schultz et al, the primary reference relied upon by the Examiner, does not disclose a passive dry powder inhaler. As defined by the Applicant in Paragraph 0023 and as known in the art, a "passive dry powder inhaler" refers to an inhalation device which relies on the patient's inspiratory effort to disperse and aerosolize a drug formulation. As further explained, a "passive dry powder inhaler" does not include inhaler devices which comprise a means for providing energy to disperse and aerosolize the drug formulation. In contrast to that which Applicant claims, Schultz et al discloses an active dry powder inhaler that relies on a motor and impeller (see column 4 lines 49-57 and column 6 lines 32-58). Hanes et

al and Radhakrishnan are not relied on to teach the use of a passive inhaler, nor do they. Accordingly, the combination of references proffered by the Examiner as obvious does not meet all limitations recited in claim 1. Therefore, the Examiner has failed to establish a *prima facie* case under 35 U.S.C. §103(a).

Furthermore, it would have not have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schultz et al in a manner that would arrive at Applicant's invention as set forth in claim 1. First, there is no motivation provided by either the references or the Examiner to modify Schultz et al from an active to a passive device. Secondly, one of ordinary skill in the art would not have found it obvious to modify Schultz et al from an active to a passive device because doing so would go expressly against the teachings of Schultz et al. As discussed throughout Schultz et al, the motor and impellar system is designed to make the Schultz et al device flow rate independent (see abstract, column 3 lines 32-40, and column 4 lines 1-2). Thus, a modification to make the active inhaler of Schultz et al into a passive inhaler would fly in the face of the teachings of Schultz et al and would not have been obvious to one having ordinary skill in the art, particularly in the absence of any motivation to do so.

For at least these reasons, claim 1 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Schultz et al, Hanes et al and Radhakrishnan. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Schultz et al in a manner that would result in the invention of claim 1 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 1 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 3-5 and 11-15, which depend from claim 1 and are not rendered unpatentable by Schultz et al,

Hanes et al and Radhakrishnan for at least the same reasons as claim 1.

In addition, independent claim 21 is not rendered unpatentable by Schultz et al, Hanes et al and Radhakrishnan. Claim 21 is to a method comprising, inter alia, loading a dry powder composition into a passive dry powder inhaler. Schultz et al does not disclose or suggest a passive dry powder inhaler, as discussed above. Furthermore, Hanes et al and Radhakrishnan do not make up for the deficiency. Accordingly, there is no *prima facie* case of obviousness under 35 U.S.C. §103(a) established against claim 21. Moreover, it would not have been obvious to modify Schultz et al in that (i) there is not motivation to make the modification and (ii) Schultz et al teaches away from any such modification.

For at least these reasons, claim 21 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Schultz et al, Hanes et al and Radhakrishnan. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Schultz et al in a manner that would result in the invention of claim 21 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 21 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 21 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 22-28 that depend from claim 21 and are not rendered unpatentable by Schultz et al, Hanes et al and Radhakrishnan for at least the same reasons as claim 21.

Independent claim 29 is not rendered unpatentable by Schultz et al, Hanes et al and Radhakrishnan, either. Claim 29 is to a method comprising, inter alia, loading a dry powder composition into a passive dry powder inhaler. Schultz et al does not disclose or suggest a passive dry powder inhaler, as discussed above. Furthermore, Hanes et al and Radhakrishnan do not make up for the deficiency. Accordingly, there is no *prima*

facie case of obviousness under 35 U.S.C. §103(a) established against claim 29. Moreover, it would not have been obvious to modify Schultz et al in that (i) there is not motivation to make the modification and (ii) Schultz et al teaches away from any such modification.

For at least these reasons, claim 29 is not properly rejectable under 35 U.S.C. §103(a) as being unpatentable over Schultz et al, Hanes et al and Radhakrishnan. The modification that would be necessary is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. There is no evidence to suggest that this is a situation where the ordinary artisan could have been motivated to modify Schultz et al in a manner that would result in the invention of claim 29 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 29 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 29 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 30-34 which depend from claim 29 and are not rendered unpatentable by Schultz et al, Hanes et al and Radhakrishnan for at least the same reasons as claim 29.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 09/851,226 in view of Schultz et al and Hanes et al.

The provisional double patenting rejection is traversed. First, since the rejection is provisional and since the present application is in condition for allowance for the reasons described above, Applicant requests withdrawal of the provisional rejection. Secondly, Schultz et al and Hanes et al do not teach a passive dry powder inhaler of the type claimed. Thus, they are not combinable with the '226 application in the manner proposed by the Examiner. Thus, Applicant requests withdrawal of the provisional

double patenting rejection.

The Examiner provisionally rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 10/141,219 in view of Schultz et al.

The provisional double patenting rejection is traversed. First, since the rejection is provisional and since the present application is in condition for allowance for the reasons described above, Applicant requests withdrawal of the provisional rejection. Secondly, Schultz et al does not teach a passive dry powder inhaler of the type claimed. Thus, it is not combinable with the '219 application in the manner proposed by the Examiner. Thus, Applicant requests withdrawal of the provisional double patenting rejection.

The Examiner provisionally rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application No. 11/187,757 in view of Schultz et al.

The provisional double patenting rejection is traversed. First, since the rejection is provisional and since the present application is in condition for allowance for the reasons described above, Applicant requests withdrawal of the provisional rejection. Secondly, Schultz et al does not teach a passive dry powder inhaler of the type claimed. Thus, it is not combinable with the '219 application in the manner proposed by the Examiner. Thus, Applicant requests withdrawal of the provisional double patenting rejection.

The Examiner rejected claims 1, 3-5, 11-15 and 21-34 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent No. 7,306,787 in view of Schultz et al.

The double patenting rejection is traversed. Schultz et al does not teach a

passive dry powder inhaler of the type claimed. Thus, it is not combinable with the '787 patent in the manner proposed by the Examiner. Thus, Applicant requests withdrawal of the double patenting rejection.

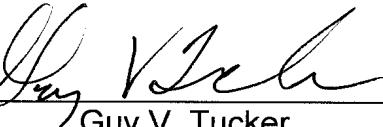
Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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